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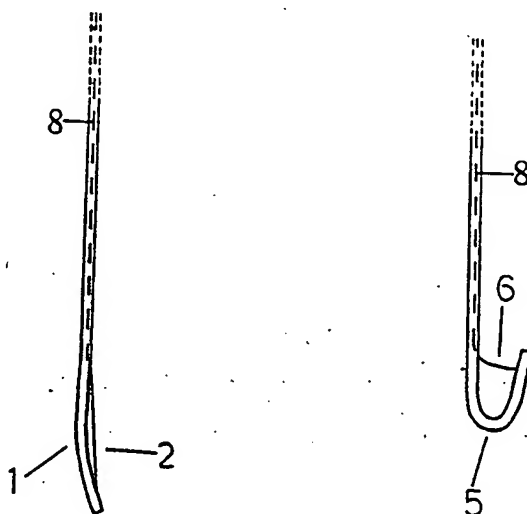
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(54) Title: STEERABLE CARDIAC CATHETER



(57) Abstract

Steerable cardiac catheter for the retrograde (via the left ventricle) catheterization of the left atrium which consists of a catheter (1, 5) that has in its proximal part a steering arm (8) which passes through the lumen of the catheter shaft, emerges a short distance from the distal end of catheter shaft and is fixed to the distal end of the catheter (1, 2, 5, 6). When the steering arm (8) is advanced (2), by external manipulations, the angle of the curve of the distal part of the shaft is increased (1), and when the steering arm (8) is retracted (6), the angle of the curve of the distal part of the catheter is closed (5). These manipulations, in combination with the appropriate rotation of the catheter shaft around its longitudinal axis, again by external manipulations, make it possible for the catheter to find access to the left atrium, when the catheter has been advanced to the left ventricle retrogradely.

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STEERABLE CARDIAC CATHETERTechnical Field

The invention concerns a cardiac catheter for the retrograde catheterization of
5 the left atrium of the heart.

Background Of The Invention

Catheterization of the left atrium presents great interest and it is performed
for diagnostic, research (function of the left atrium, hemodynamic studies,
secretory capacity) and therapeutic (balloon mitral valvuloplasty) purposes.
10 Particularly, catheterization of the left atrium became a necessity with the
establishment of percutaneous mitral valvuloplasty as an important therapeutic
modality for the nonsurgical treatment of rheumatic mitral stenosis. Retrograde
(via the left ventricle) catheterization of the left atrium, however, presents certain
difficulties, and has the risk of damage to the subvalvular apparatus. These result
15 from the position of the mitral ring relative to the left atrial cavity. To approach the
mitral orifice, the catheter must bend through a large angle. Apart from this, the
mitral subvalvular system itself (papillary muscles, cordae tendineae) impedes
access to the left atrium. The first attempt for the retrograde catheterization of the
left atrium (E. Shirey et al, Retrograde transaortic and mitral valve catheterization.
20 Am J Cardiol 1966;18:745), did not catch on, probably because it was unsuccessful in
many cases, particularly in patients with mitral stenosis. Attempts of balloon mitral
valvuloplasty using a purely retrograde route by means of conventional (Buchler
JR, et al. Percutaneous mitral valvuloplasty in rheumatic stenosis by isolated
transarterial approach: A new feasible technique. Jpn Heart J 1987;28:790) or
25 preshaped (Orme EC, et al. Balloon mitral valvuloplasty via retrograde left atrial
catheterization. Am Heart J 1989;117:680) catheters, have met with limited success.
Thus, the inability to achieve a controlled retrograde approach to the mitral valve
and, through it, to the left atrium, has led to the universal adoption of the antegrade
transseptal approach for left atrial catheterization, usually with concomitant
30 dilatation of the interatrial septum. However, this method is rather complicated,
requires great skills on the part of the operator, and may be accompanied by

serious complications, such as perforation of the heart and hemodynamically significant left-to-right atrial shunt. (for example: The National Heart, Lung and Blood Institute Balloon Valvuloplasty registry Participants: Multicenter experience with balloon mitral commissurotomy. NHBLI balloon valvuloplasty registry report 5 on immediate and 30-day follow-up results. Circulation 1992;85:448 / Crawford MH. Iatrogenic Lutembacher's syndrome revisited. Circulation 1990;81:1422-1424 / Baim DS, Grossmann W. Percutaneous approach and transseptal catheterization. In: Grossman W, ed. Cardiac Catheterization and Angiography. Philadelphia: Lea and Febiger, 1986:71-75). For these reasons, a simple method for the retrograde 10 catheterization of the left atrium would be desirable.

Summary of the invention

The present invention is a safe and effective means for the successful retrograde catheterization of the left atrium that bypasses the serious disadvantages of the transseptal catheterization. The present invention has the advantage that 15 manipulation of a steering arm enables the configuration of the catheter tip to be changed by remote control, so that the tip may assume different forms. A forwardly movement of the steering arm along the longitudinal axis of the shaft increases the angle of the curve of the distal part of the shaft and the rearwardly movement of the steering arm along the longitudinal axis of the shaft reduces the 20 angle of the distal part of the shaft. This, in combination with the appropriate rotation of the catheter shaft around its longitudinal axis, again by external manipulations, makes it possible for the catheter tip to point towards the mitral valve annulus and find access to the left atrium, when the catheter has been advanced to the left ventricle retrogradely. The main advantages of the steerable 25 cardiac catheter for the retrograde catheterization of the left atrium is its effectiveness (offers a consistent entering to the left atrium under any circumstances) and safety (avoids damage to the subvalvular apparatus while it obviates the need for transseptal catheterization and its inherent complications). For these reasons, the present invention provides a safe and effective means for the 30 retrograde catheterization of the left atrium for diagnostic, research and therapeutic purposes.

Brief Description Of The Drawings

FIGURE 1 shows the distal of a catheter embodying the present invention in a straightened configuration;

FIGURE 2 shows the distal part of the same catheter as in FIGURE 1, but in an intermediately curved configuration;

FIGURE 3 shows the distal part of a catheter of this invention in its completely curved configuration;

FIGURE 4 shows the proximal part of a catheter provided with a steering system that enables the configuration of the distal part of the catheter to be altered by remote control thereof as shown in FIGURES 1-3, as above

Description Of The Preferred Embodiment

The present invention is described in detail below with reference to the aforementioned drawings which illustrate one specific embodiment.

The drawings illustrate the steerable catheter for the catheterization of the left atrium, which consists of a cardiac catheter (1,3,5) that has in its proximal part (7) a steering arm or wire (8) which passes through the lumen of the catheter shaft and emerges a short distance from the distal end of catheter shaft. The distal end region of the the arm or wire is attached to the distal end of the catheter as shown in FIGURE 1. When the steering arm or wire (8) is advanced, by external manipulations, the angle of the curve of the distal part of the shaft is increased, until the distal part of the catheter acquires, at the forwardmost advancement of the steering arm or wire (2), a straightened configuration (1) which facilitates insertion of the catheter to the femoral artery and advancement to the left ventricle. When the steering arm or wire (8) is retracted (4), again by external manipulations, the angle of the curve of the distal part of the catheter is closed (3), up to the completely curved configuration (5) at the rearwardmost retraction of the steering arm or wire (6). These manipulations, in combination with the appropriate rotation of the catheter shaft around its longitudinal axis, again by external manipulations, make it possible for the catheter tip to point towards the mitral valve annulus and find access to the left atrium, when the catheter has been advanced to the left ventricle retrogradely. To remove the catheter from the patient, the steering wire (8) is

advanced and the distal part of the catheter is straightened (1).

The foregoing discussion and the accompanying drawings are intended to be illustrative and are not to be taken as limiting. Still other variations within the spirit and scope of this invention are possible and will readily present themselves to those
5 skilled in the art.

CLAIMS

A steerable cardiac catheter for the catheterization of the left atrium suitable for diagnostic, research and therapeutic purposes, which comprises an elongated, flexible hollow shaft; and a steering arm for said shaft so that a forwardly movement of the steering arm along the longitudinal axis of the shaft increases the angle of the curve of the distal part of the shaft and the rearwardly movement of the steering arm along the longitudinal axis of the shaft reduces the angle of the distal part of the shaft.

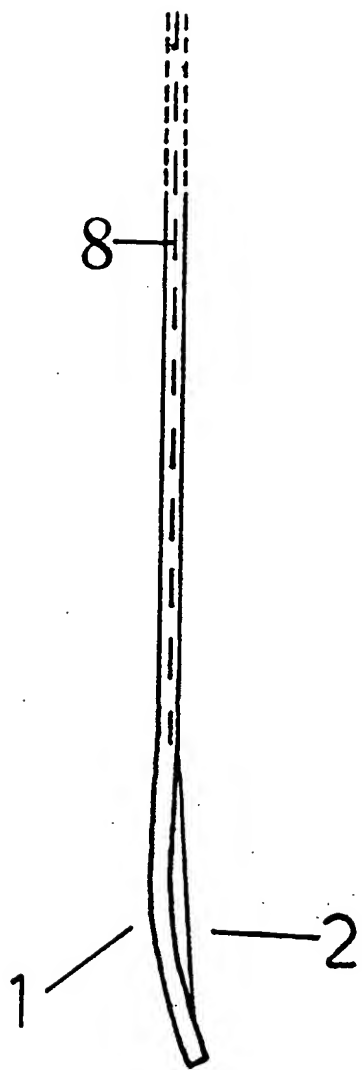


Figure 1

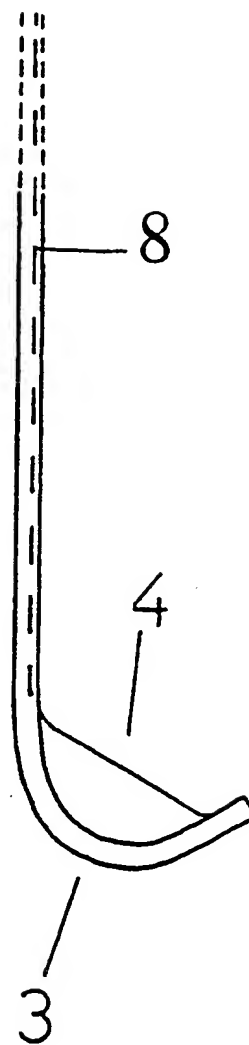


Figure 2

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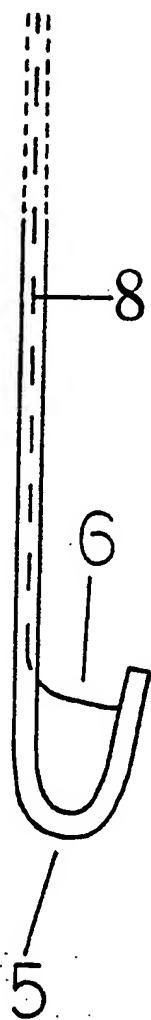


Figure 3

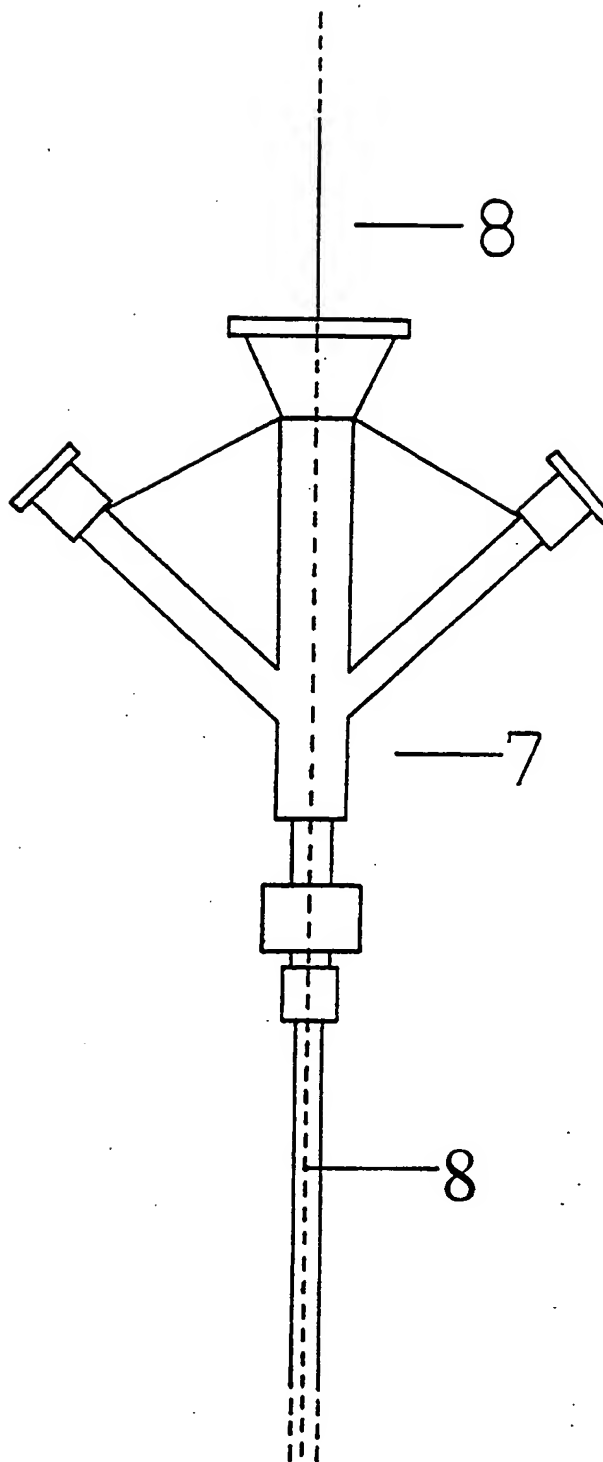


Figure 4

INTERNATIONAL SEARCH REPORT

International application No.

PCT/GR 93/00015

A. CLASSIFICATION OF SUBJECT MATTER

IPC5: A61M 25/01

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC5: A61M

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	FR, A, 834690 (LUDWIG ZEISS), 29 November 1938 (29.11.38), see e.g. le fil de traction 1 and la partie de fil 10 and adherent text --	1
X	DE, A1, 3920707 (FOERSTER, ERNST ET AL), 10 January 1991 (10.01.91), see especially Steuerdraht 8 in fig 1 and adherent text --	1
X	US, A, 3119392 (KARL-LUDWIG ZEISS), 28 January 1964 (28.01.64), see especially tilting thread 10 in fig 4 and adherent text --	1

☒ Further documents are listed in the continuation of Box C.

☒ See patent family annex.

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Date of the actual completion of the international search

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Name and mailing address of the International Searching Authority Authorized officer



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INTERNATIONAL SEARCH REPORT

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C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US, A, 2574840 (J. PIERI ET AL), 13 November 1951 (13.11.51), see cable 6 and adherent text --	1
X	US, A, 4861336 (HELZEL), 29 August 1989 (29.08.89), see especially pulling mechanism 4 in fig 1 and adherent text --	1
X	EP, A1, 0274705 (FRIMBERGER, ERINTRUD), 20 July 1988 (20.07.88), see especially Draht 3 in fig 2 and adherent text --	1
X	WO, A1, 8911306 (EIDE, TERJE), 30 November 1989 (30.11.89); see especially string 8 and adherent text --	1
X	WO, A1, 9101772 (RADI MEDICAL SYSTEMS AB), 21 February 1991 (21.02.91), see especially pull lines 8,8' and adherent text -----	1

INTERNATIONAL SEARCH REPORT
Information on patent family members

01/10/93

International application No.

PCT/GR 93/00015

Patent document cited in search report		Publication date	Patent family member(s)		Publication date
FR-A-	834690	29/11/38	NONE		
DE-A1-	3920707	10/01/91	NONE		
US-A-	3119392	28/01/64	NONE		
US-A-	2574840	13/11/51	NONE		
US-A-	4861336	29/08/89	DE-A-	3710913	13/10/88
EP-A1-	0274705	20/07/88	DE-A-	3643362	23/06/88
			DE-A-	3777135	09/04/92
			JP-A-	63288150	25/11/88
			US-A-	4846175	11/07/89
WO-A1-	8911306	30/11/89	NONE		
WO-A1-	9101772	21/02/91	AU-A-	6067390	11/03/91
			SE-B,C-	468306	14/12/92
			SE-A-	9003758	01/02/91